

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

IN RE: BRIMONIDINE PATENT
LITIGATION

MDL Docket No. 07-md-1866 GMS

MEMORANDUM

I. INTRODUCTION

In this consolidated patent infringement action, the plaintiff alleges that the defendants' proposed generic pharmaceutical products infringe the asserted claims of the patents-in-suit.¹ (D.I. 1.) The court held an eight-day bench trial in this matter on March 9 through March 18, 2009. (D.I. 227-34.) Presently before the court are the parties' post-trial proposed findings of fact and conclusions of law, and post-trial motions for judgment pursuant to Fed. R. Civ. P. 52(c) (the "Rule 52(c) motions").

Pursuant to Fed. R. Civ. P. 52(a), and after having considered the entire record in this case and the applicable law, the court concludes that: (A) the defendants' proposed generic products infringe the asserted claims of the patents-in-suit; (B) the patents-in-suit are not invalid; (C) the patents-in-suit are not unenforceable; and that (D) an award for attorneys' fees and costs is not warranted in this case.² The court also grants the plaintiff's Rule 52(c) motion and denies

¹ The plaintiff in this action is Allergan, Inc. ("Allergan"). (D.I. 1.) There are two sets of defendants that remain in this action: (1) Exela PharmSci, Inc. and Exela PharmSci Pvt., Ltd. (collectively, "Exela") and (2) Apotex, Inc. and Apotex Corp. (collectively, "Apotex"). (*Id.*)

² The court makes these findings based on substantial evidence in the entire record and after hearing the trial testimony first hand. Because the court had the benefit of observing witness demeanor in the courtroom, it was possible to make credibility determinations that aided the

Exela's Rule 52(c) motion. These findings of fact and conclusions of law are set forth in further detail below.

II. FINDINGS OF FACT

A. The Parties

1. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2525 DuPont Drive, Irvine, California 92612. (D.I. 190, Tab 1 at ¶ 1.)

2. Defendant Apotex, Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9. (*Id.* at ¶ 22.)

3. Defendant Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326. (*Id.* at ¶ 23.)

4. Defendant Exela PharmSci, Inc. is an entity organized under the laws of the State of Virginia, and is headquartered at 11710 Plaza America Dr., Suite 2000, Reston, Virginia 20190. (*Id.* at ¶ 27.)

5. Defendant Exela PharmSci Pvt., Ltd. is an entity organized under the laws of the country of India with headquarters in Hyderabad, India. Exela PharmSci Pvt., Ltd. is jointly owned by Exela PharmSci, Inc. and Exela Holdings, Inc. (D.I. 190, Tab 1 at ¶ 28.)

6. Defendant Paddock Laboratories, Inc. ("Paddock") is a corporation organized and

court in resolving conflicting testimonial evidence and, in part, in determining which evidence to credit and which evidence to discredit.

existing under the laws of the State of Minnesota, with its headquarters and principal place of business at 3940 Quebec Avenue North, Minneapolis, MN 55427. (*Id.* at ¶ 29.)

7. Defendant PharmaForce, Inc. (“PharmaForce”) is a corporation organized and existing under the laws of the State of Delaware, with its headquarters and principal place of business at 960 Crupper Avenue, Columbus, Ohio 43229. (*Id.* at ¶ 30.)

8. Allergan, Paddock, and PharmaForce entered into a settlement agreement and submitted a consent judgment to the court on January 20, 2009. (D.I. 168.) The court entered an order granting consent judgment on February 25, 2009. (D.I. 221.)

B. The Patents-In-Suit

9. Brimonidine tartrate (5-bromo-6-(2-imidazolylamino) quinoxaline tartrate) (“brimonidine tartrate” or “brimonidine”) is an alpha-2-adrenergic agonist drug compound that is used in ophthalmic solutions for the treatment of glaucoma. (D.I. 190, Tab 1 at ¶ 3.)

10. Allergan markets its brimonidine tartrate products under the ALPHAGAN P® brand name for use in the treatment of glaucoma. (*Id.* at ¶¶ 3, 5.) Specifically, Allergan’s ALPHAGAN P® 0.1% and 0.15% brimonidine ophthalmic solution products are indicated for the lowering of intraocular pressure in patients with open-angle glaucoma or ocular pressure. (*Id.*)

11. The “patents-in-suit” collectively consist of the following: U.S. Patent Nos. 6,627,210 (the “210 patent”), 6,641,834 (the “834 patent”), 6,673,337 (the “337 patent”), 6,562,873 (the “873 patent”), and 5,424,078 (the “078 patent”). Allergan owns all five patents-in-suit. (D.I. 190, Tab 1 at 2-3.)

12. Orest Olejnik, Ph.D. (“Dr. Olejnik”) and Edward D.S. Kerslake, Ph.D. (“Dr.

Kerslake”) are the named inventors on the ‘210, ‘834, ‘337, and ‘873 patents. (*Id.* at 2.)

13. The ‘210 patent is entitled “Compositions Containing Alpha-2-Adrenergic Agonist Components.” (D.I. 190, Tab 1 at 2.) The ‘210 patent issued on September 30, 2003. (*Id.*) The ‘210 patent generally covers therapeutically effective compositions containing brimonidine and a polyanionic solubility component (“SEC”), such as carboxymethylcellulose (“CMC”). (*Id.*)

14. The ‘834 patent is entitled “Compositions Containing Alpha-2-Adrenergic Agonist Components.” (D.I. 190, Tab 1 at 2.) The ‘834 patent issued on November 4, 2003. (*Id.*) The ‘834 patent generally covers therapeutically effective ophthalmic compositions comprising up to about 0.15% brimonidine with a pH of about 7.0 or greater, where the brimonidine is soluble in the composition at room temperature. (D.I. 190, Tab 7.1 at 14.)

15. The ‘337 patent is entitled “Compositions Containing Alpha-2-Adrenergic Agonist Components.” (D.I. 190, Tab 1 at 3.) The ‘337 patent issued on January 6, 2004. (*Id.*) The ‘337 patent generally covers therapeutically effective ophthalmic compositions containing alpha-2-adrenergic agonists and an anionic SEC other than cyclodextrin. (D.I. 190, Tab 7.1 at 15.)

16. The ‘210, ‘834, and ‘337 patents all share a common specification. (D.I. 190, Tab 1 at 3.)

17. The ‘873 patent is entitled “Compositions Containing Therapeutically Active Components Having Enhanced Solubility.” (D.I. 190, Tab 1 at 2.) The ‘873 patent issued on May 13, 2003. (*Id.*) The ‘873 patent generally covers therapeutically effective compositions containing alpha-2-adrenergic agonists, CMC as an SEC, and an oxy-chloro preservative

component. (D.I. 190, Tab 7.1 at 14.)

18. The '078 patent is entitled "Aqueous Ophthalmic Formulations and Methods for Preserving Same." (D.I. 190, Tab 1 at 3.) The '078 patent issued on June 13, 1995. (*Id.*) The named inventors on the '078 patent are Anthony J. Dziabo ("Dziabo") and Paul S. Ripley ("Ripley"). (*Id.*) The '078 patent generally covers aqueous ophthalmic formulations preserved by stabilized chlorine dioxide, buffered to a pH of about 6.8 to about 8 with tonicity components to maintain an osmolality of at least about 200 mOsmol/kg. (D.I. 190, Tab 7.1 at 106.)

19. One or more of the claims of each of the patents-in-suit covers each of the ALPHAGAN P® products. Specifically, ALPHAGAN P® 0.15% is encompassed within the scope of at least the following claims of the patents-in-suit: claims 1-5, 7-9, 12-23, 25-27, 29-31, and 33-34 of the '210 patent; claims 1-7, 10-16, 20, and 22 of the '834 patent; claims 5 and 8 of the '337 patent; claims 12, 25, 26, 31, 33, and 45 of the '873 patent; and claims 1-12 and 14-18 of the '078 patent. ALPHAGAN P® 0.1% is encompassed within the scope of at least the following claims of the patents-in-suit: claims 1-5, 7-9, 12-23, 25-27, 29-31, and 33-34 of the '210 patent; claims 1-2, 5-7, 10-11, 14-16, 20, and 22 of the '834 patent; claims 5 and 8 of the '337 patent; claims 12, 25, 26, 31, 33, and 45 of the '873 patent; and claims 1-12 and 14-18 of the '078 patent.³ (D.I. 190, Tab 1 at 3-4.) Refresh Tears® is an artificial tear product made by Allergan that lubricates and moisturizes dry eyes. (D.I. 190, Tab 7.1 at 33.) Refresh Tears® contains PURITE® as a preservative. (*Id.*) PURITE® is a stabilized chlorine dioxide compound

³ The claims listed in this paragraph are referred to collectively throughout this memorandum as the "asserted claims."

that is predominantly composed of chlorite ion.⁴ (*Id.*) Since at least 1998, Refresh Tears® has been formulated with a pH of 7.7. (*Id.*)

20. The effective filing date of the '210, '834, '337, and ''873 patents is July 14, 2000. (D.I. 190, Tab 7.1 at 13-15.) The effective filing date of the '078 patent is November 29, 1988. (*Id.*)

C. The Accused Products

21. On February 12, 2007, Allergan received a paragraph IV letter dated February 8, 2007, indicating that Exela had submitted ANDA No. 78-590 with the FDA under section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of a 0.15% brimonidine tartrate ophthalmic solution prior to the expiration of the patents-in-suit. (D.I. 190, Tab 1 at 6.) Exela's paragraph IV letter states that the product in ANDA No. 78-590 would not infringe certain claims of the patents-in-suit, and that all of the claims of the patents-in-suit are invalid. (*Id.*) The paragraph IV letter further states that the pH of the proposed product in ANDA No. 78-590 is "between 6.5 and 6.7." (PTX-026 at XLA000372.)

22. ANDA No. 78-590 seeks approval to market a generic product for the lowering of intraocular pressure ("IOP") in patients with open-angle glaucoma or ocular hypertension. (D.I. 190, Tab 1 at 7.) The proposed product in ANDA No. 78-590 is formulated as a topically administrable aqueous solution. (*Id.* at 6.) The active ingredient in the proposed product in ANDA No. 78-590 is brimonidine tartrate. (*Id.*) The proposed product in ANDA No. 78-590 has the same dosage form, route of administration, dosing regimen, and indication as

⁴ The PURITE® preservative is covered by the '078 patent. (D.I. 190, Tab 7.1 at 33.)

ALPHAGAN P®. (*Id.* at 6-7.)

23. In its original submission to the FDA, Exela indicated that the proposed product in ANDA No. 78-590 had a manufacturing pH range of 6.5 to 6.7 and a release specification range of 6.2 to 6.5. (PTX-030 at XLA000400-01.) Exela's proposed labeling for the product, however, stated a pH range of 5.5 to 6.7. (PTX-026 at XLA000372.) In a June 20, 2007 bioequivalence deficiency letter, the FDA rejected Exela's request for a bioequivalency waiver based on a proposed product with a pH range of 5.5 to 6.7. (PTX-029 at XLA000395.) In the deficiency letter, the FDA noted that Exela had not shown that the difference between the pH of the proposed product in ANDA No. 78-590, *i.e.*, 5.5 to 6.7, and ALPHAGAN P®, *i.e.*, 6.6 to 7.4, "ha[d] no significant impact on the bioavailability or efficacy of the drug." (*Id.*)

24. In response to the FDA's deficiency letter, in an August 9, 2007 letter to the FDA, Exela stated that it believed that the FDA's concerns resulted from "confusion concerning the pH range of Exela's product," and that it wished to "correct the record with respect to the pH range of its proposed drug product." (PTX-030 at XLA000400-01.) In correcting the record, Exela stated that it intended to "clarify the proposed labeling" to reflect that the lower end of the proposed product's pH range would be 6.5 rather than 5.5. (*Id.*) Likewise, as noted above, in its February 8, 2007 paragraph IV letter to Allergan, Exela also stated to the FDA that the pH of the proposed product was between 6.5 and 6.7. (PTX-030 at XLA000404; EDTX-089 at XLA011804.)

25. Allergan filed suit against Exela alleging infringement of the '834 patent under 35 U.S.C. § 271(e)(2) on March 26, 2007, within 45 days of receipt of Exela's Paragraph IV letter. (D.I. 190, Tab 1 at 6.)

26. On April 30, 2007, Allergan received a paragraph IV letter dated April 26, 2007, indicating that Apotex had submitted two Abbreviated New Drug Applications, *i.e.*, ANDA Nos. 78-479 and 78-480, with the FDA under section 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of a 0.15% brimonidine tartrate ophthalmic solution and a 0.1% brimonidine tartrate ophthalmic solution prior to the expiration of the patents-in-suit. (D.I. 190, Tab 1 at 4.) Apotex's paragraph IV letter states that the products in ANDAs Nos. 78-479 and 78-480 would not infringe certain claims of the patents-in-suit and that all of the claims of the patents-in-suit are invalid. (*Id.*)

27. Allergan filed suit against Apotex alleging infringement of the patents-in-suit under 35 U.S.C. § 271(e)(2) on May 21, 2007, within 45 days of receipt of Apotex's paragraph IV letter. (D.I. 190, Tab 1 at 4.)

D. Procedural History

28. On March 26, 2007, Allergan filed suit against Exela in the Central District of California for infringement of the '834 patent. (D.I. 190, Tab 1 at 6.) On May 21, 2007, Allergan filed a second suit against Apotex in this court for infringement of all of the patents-in-suit, including the '834 patent. (*Id.* at 4.) On August 21, 2007, the U.S. Judicial Panel on Multidistrict Litigation (the "MDL panel") transferred Allergan's suit against Exela in the Central District of California to this court, and consolidated it with Allergan's pending action against Apotex in this court. (D.I. 1.)

29. The court held a *Markman* hearing in this consolidated matter on October 6, 2008. Following that hearing, the court issued an order construing the disputed claim terms of the

patents-in-suit.⁵ (D.I. 138.)

30. The court held an eight-day bench trial in this matter on March 9 through March 18, 2009. (D.I. 227-34.) On April 17, 2009, the parties submitted simultaneous post-trial proposed findings of fact and conclusions of law. (D.I. 235-37.) Exela filed its Rule 52(c) motion for non-infringement on March 12, 2009. (D.I. 223.) Allergan filed its Rule 52(c) motion regarding certain “prior art references or combinations of references not used at trial” on April 27, 2009. (D.I. 244.) The parties completed briefing on these motions on May 1, 2009. (D.I. 225, 250.)

E. Parties’ Contentions

31. Allergan contends that the asserted claims of patents-in-suit are valid and enforceable, and that both Exela’s and Apotex’s proposed generic brimonidine products infringe the asserted claims of the patents-in-suit.⁶ (D.I. 190, Tab 2 at ¶ 1.) Allergan also contends that it is entitled to an award of attorneys’ fees and costs under 35 U.S.C. § 285. (*Id.* at ¶ 15.)

32. Both Exela and Apotex contend that the patents-in-suit are invalid for a myriad of reasons, which include: obviousness, non-enablement, failure of written description, failure to disclose a best mode, indefiniteness, lack of utility, inoperability and incorrect inventorship. (D.I. 190, Tab 2 at ¶¶ 2-13.) In addition, Apotex contends that the asserted claims of the ‘078 patent are unenforceable due to inequitable conduct. (*Id.* at ¶ 1.) Both defendants claim that they

⁵ The court fully adopts and incorporates herein by reference, the above-mentioned claim construction order entered in this case. (D.I. 138.)

⁶ Allergan asserts all five patents-in-suit against Apotex, but only the ‘834 patent against Exela. (D.I. 236 at 6.) Regarding Allergan’s infringement claims, Apotex does not dispute that its 0.15% brimonidine product infringes all of the asserted claims of the patents-in-suit. (*Id.* at 6 n.2.) Apotex also does not dispute that, with the exception of claims 3, 4, 12 and 13, its 0.1%

are entitled to attorneys' fees and costs under 35 U.S.C. § 285. (*Id.* at ¶ 15.)

III. CONCLUSIONS OF LAW

33. The court has subject matter jurisdiction over this matter pursuant to 28 U.S.C. §§ 1331, 1338 and 2201. Venue is proper in this court under 28 U.S.C. §§ 1391 and 1400(b).

34. After having considered the entire record in this case, the substantial evidence in the record, the parties' post-trial submissions, and the applicable law, the court concludes that: (A) both Apotex's and Exela's proposed generic brimonidine products literally infringe the asserted claims of the patents-in-suit; (B) the patents-in-suit are not invalid; (C) the patents-in-suit are not unenforceable due to inequitable conduct; (D) an award for attorneys' fees and costs is not warranted in this case; (E) Allergan's Rule 52(c) motion should be granted, and that Exela's Rule 52(c) motion should be denied in its entirety.

A. Infringement

35. Patent infringement is making, using, importing, offering to sell, or selling a patented invention without authority. 35 U.S.C. § 271(a). Under the Hatch-Waxman Act, Pub. L. No. 98-417, 98 Stat. 1585 (codified as amended at 21 U.S.C. § 355; 35 U.S.C. §§ 156, 271, 282), it is an act of infringement to submit an ANDA for a drug claimed in a patent. 35 U.S.C. § 271(e)(2)(A).

36. A patent infringement analysis entails two steps: "(1) claim construction to determine the scope of the claims, followed by (2) determination of whether the properly construed claim encompasses the accused device." *Bai v. L & L Wings, Inc.*, 160 F.3d 1350, 1353 (Fed. Cir.1998) (citations omitted).

brimonidine product infringes all of the asserted claims of the '834 patent. (*Id.* at 6.)

37. The first step, claim construction, is a matter of law for the court to decide and involves determining the meaning and scope of the patent claims asserted to be infringed. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372, 116 S. Ct. 1384, 1387 (1996).

38. The second step, determination of infringement, is a question of fact. *Bai*, 160 F.3d at 1353. A patentee must establish literal infringement by a preponderance of the evidence. *See, e.g., Braun Inc. v. Dynamics Corp.*, 975 F.2d 815, 819 (Fed. Cir.1992). “To establish literal infringement, every limitation set forth in a claim must be found in [the] accused product, exactly.” *Southwall Tech., Inc. v. Cardinal IG Co.*, 54 F.3d 1570, 1575 (Fed. Cir.1995).

39. Under the second step of the infringement analysis, the plaintiff bears the burden of proving that the accused product meets each and every limitation of the construed claims by a preponderance of the evidence. *Catalina Lighting, Inc. v. Lamps Plus, Inc.*, 295 F.3d 1277, 1285 (Fed. Cir. 2002). Where the act of infringement is the filing of an ANDA, the analysis is a hypothetical one, comparing the asserted claims against the product that is likely to be sold should the FDA approve the application. *Bayer AG v. Elan Pharm. Research Corp.*, 212 F.3d 1241, 1248-49 (Fed. Cir. 2000). “This hypothetical inquiry is properly grounded in the ANDA application and the extensive materials typically submitted in its support.” *Id.* at 1248 (quotation omitted). Therefore, it is proper for the court to consider the ANDA itself, materials submitted by the ANDA applicant in support of its ANDA, and any other pertinent evidence. *Id.* at 1248-49.

40. Here, after applying the court’s claim construction to the asserted claims of the patents-in-suit,⁷ and considering the record evidence in this case, the court concludes that both

⁷ The court construes the term “about” as having its ordinary meaning of “approximately.” (D.I.

Apotex and Exela infringe the asserted claims of the patents-in-suit under 35 U.S.C. § 271(e)(2). Specifically, the court concludes that Apotex's proposed generic brimonidine products infringe the asserted claims of the patents-in-suit by a preponderance of the evidence,⁸ and that Exela's proposed generic brimonidine product infringes the asserted claims of the '834 patent by a preponderance of the evidence.

41. Exela's proposed generic brimonidine product infringes each and every limitation of claim 1 of the '834 patent.⁹ Exela's proposed generic brimonidine product is "a therapeutically effective ophthalmic composition." (The '834 patent at claim 1.) It also contains "up to about 0.15% (w/v) of [brimonidine] tartrate" and is "soluble . . . at about 21°C." (*Id.*)

42. Exela's generic brimonidine product has a pH of "about 7.0 or greater." (The '834 patent at claim 1.) The court credits the testimony of Allergan's expert in this regard. At trial, Allergan's infringement expert, Valentino Stella, Ph.D. ("Dr. Stella") testified and explained in detail, how and why Exela infringes all of the asserted claims of the '834 patent, including claim 1. Specifically, Dr. Stella testified that Exela's proposed brimonidine product meets all of limitations of claim 1 of the '834 patent on an element-by-element, limitation-by-

138 at 2.) The court construes the term "therapeutically effective aqueous ophthalmic composition" as having its ordinary meaning. (*Id.* at 1.)

⁸ Because Apotex stipulates that its ANDA Nos. 78-479 and 78-480 infringe the asserted claims of the patents-in-suit, the court does not address this issue in any further detail in its analysis.

⁹ Claim 1 of the '834 patent teaches:

A therapeutically effective aqueous ophthalmic composition comprising:

up to about 0.15% (w/v) of [brimonidine] tartrate, the composition having a pH of about 7.0 or greater, and the [brimonidine] tartrate being soluble in the composition at about 21°C.

limitation basis. (D.I. 230 at 723:8-724:7.) Dr. Stella also credibly explained how the Exela product infringes the “having a pH of about 7.0 or greater” limitation of claim 1 of the ‘834 patent. (*Id.* at 743:24-744:7.) Citing to information contained in Exela’s ANDA, as well as information provided in the extensive materials Exela submitted to the FDA in support of its ANDA, Dr. Stella concluded that: (1) the low end of the pH range of Exela’s proposed product is, in fact, 6.5, and that (2) due to “pH drift,” Exela must manufacture its product at or near pH 7.0 to keep the pH of its product above 6.5. (*Id.* at 737:14-735:8.) The court agrees. The court finds that each of these conclusions are well-supported by a preponderance of the evidence in the record.

43. The court, however, is not convinced by Exela’s contention that the pH of its product is “always within 5.5-6.7.” (D.I. 235 at 3.) Indeed, Exela’s own communications and submissions to the FDA in support of its ANDA undermine this contention. Specifically, in its paragraph IV letter, Exela stated that the pH of its proposed product is between 6.5 and 6.7. (PTX-030 at XLA000400-01.) In addition, in its August 9, 2007 letter submitted to the FDA, Exela confirmed that the lower end of the pH range of its proposed product is “6.5 rather than 5.5.” (*Id.*) Exela also indicated that the pH of its product was between 6.5 to 6.7 in a buffer capacity study performed by its infringement expert, Ashim Mitra, Ph.D. (“Dr. Mitra”), and submitted to the FDA in support of ANDA No. 78-590. (*Id.* at XLA000404.) Based on its ANDA application and the extensive materials Exela submitted in support of its ANDA, the court concludes that the pH of Exela’s proposed generic brimonidine product is not always within 5.5 to 6.7. *See Bayer*, 212 F.3d at 1248-49 (noting that it is proper for the court to consider the ANDA itself and those materials submitted by the ANDA applicant in support of its

ANDA). The court is, therefore, not persuaded by Exela's non-infringement arguments in this regard.

44. Based on the entire record in this case, including the expert testimony and evidence presented at trial concerning the issue of pH drift, the court further concludes that Exela must manufacture its proposed product at a pH of about 7.0 or greater in order to keep the product at a pH above 6.5; and, thus, infringes the "about 7.0 or greater" limitation in claim 1 of the '834 patent. In particular, the long-term stability data Exela submitted to the FDA in support of its ANDA shows a drop of up to 0.5 pH units over the course of six months, *i.e.*, from 6.7 to 6.2. (D.I. 230 at 733:1-734:23, 735:23-736:6, 736:22-738:8.) Likewise, the accelerated stability data submitted to the FDA by Exela as part of its ANDA also shows a similar pH drop in Exela's proposed product over a three month period. (*Id.* at 738:16-740:3) In addition, as Allergan correctly notes, data from Exela's own development work relating to ANDA 78-590 also reflect a pH drift from an initial pH of 7.08 down to a pH of 6.59. (*Id.*)

45. Further, Exela admits that it used a product with a "pH of about 7.0 or greater," *i.e.*, 6.9, in the animal bioequivalence study it submitted to the FDA as part of its ANDA. (D.I. 230 at 740:4-23.) Having considered the pH stability data, the pH of the product used in the animal bioequivalence study that Exela submitted to the FDA in its ANDA, as well as the data from Exela's own development work, and the expert testimony regarding pH drift, the court is persuaded that Exela must manufacture its proposed product at a pH of about 7.0 or greater.

46. The court is not persuaded by the testimony of Exela's experts regarding the pH range of its proposed product for several reasons. First, as Allergan correctly notes, Exela's infringement expert, Dr. Mitra concedes that Exela's proposed brimonidine product essentially

meets all but the pH element of claim 1 of the '834 patent. (D.I. 231 at 984:1-4; D.I. 230 at 723:8-724:7.) Dr. Mitra also admits that for his expert report and his deposition taken in this case, he relied on Exela's August 9, 2007 letter to the FDA indicating a pH range for the proposed product of 6.5 to 6.7. (D.I. 232 at 1125:9-1126:9.) Second, in contrast to Dr. Stella's testimony and the other evidence Allergan presented at trial concerning the manufacturing data and pH stability data contained in Exela's ANDA, the court is not persuaded by the testimony of Exela's witness, Phanesh Koneru, Ph.D. ("Dr. Koneru"). The court is not convinced that Exela presented sufficient evidence to rebut the testimony and evidence presented by Allergan regarding the manufacturing pH of the proposed product, pH stability, and pH drift.

47. The court is also not persuaded by the expert testimony offered by Exela concerning the differences between the "compounding/manufacturing pH," the "release pH," and the "stability/shelf-life pH" of Exela's proposed product. Specifically, the court is not convinced that this testimony fully addresses and rebuts Allergan's argument that Exela must manufacture its product at a pH of about 7.0 or greater, in part, in order to compensate for pH drift. Accordingly, the court concludes that Exela proposed generic brimonidine product literally infringes each and every element and limitation of claim 1 of the '834 patent.

48. In addition to infringing claim 1 of the '834 patent, the court also concludes that Exela infringes all of the remaining asserted claims of the '834 patent. The preponderance of the evidence in the record confirms that the proposed Exela product contains 0.15% brimonidine -- thus, infringing dependent claims 2, 3, 4, 11, 12 and 13 of the '834 patent. The record evidence also confirms that the proposed Exela product: (1) does not contain "any anionic cellulosic derivative, including CMC," as set forth in claims 8, 9, 17 and 18, and that it (2) does contain

benzalkonium chloride (“BAK”), “a quaternary ammonium preservative” that meets the limitations of claims 6 and 19-21. (D.I. 230 at 747:8-748:25.) The court concludes therefore that Exela’s proposed product meets all of the limitations of dependent claims 6, 8-9, 17-18, and 19-21 of the ‘834 patent.

49. Because the court finds that each and every element and limitation of the asserted claims of the ‘834 patent are present in Exela’s proposed generic brimonidine product, the court concludes that Exela’s accused product literally infringes all of the asserted claims of the ‘834 patent.

B. Invalidity

50. The defendants have failed to prove by clear and convincing evidence that the patents-in-suit are invalid. Specifically, the defendants have failed to show by clear and convincing evidence that the patents-in-suit are invalid on any of the following grounds: (i) obviousness, (ii) non-enablement, (iii) failure of written description, (iv) failure to disclose a best mode, (v) indefiniteness, (vi) lack of utility/operability, or (vii) incorrect inventorship.¹⁰

i. Obviousness

51. 35 U.S.C. § 103 provides, that a patent may not be obtained “if the differences between the subject matter sought to be patented and the prior art such that the subject matter as a whole would have been obvious to a person having ordinary skill in the art.” Obviousness is a question of law that is predicated upon several factual inquiries. *Richardson-Vicks v. Upjohn Co.*, 122 F.3d 1476, 1479 (Fed. Cir. 1997). Specifically, the trier of fact must consider four

¹⁰ The court notes that Apotex offered no expert testimony in support of any of the defenses it raises under 35 U.S.C. § 112. In support of its § 112 allegations, however, Exela offered the testimony of both Nicholas Delamere, Ph.D. (“Dr. Delamere”) and Dr. Mitra.

issues: (1) the scope and content of the prior art; (2) the level of ordinary skill in the art; (3) the differences between the claimed subject matter and the prior art; and (4) secondary considerations of non-obviousness, such as commercial success, long felt but unsolved need, failure of others, and acquiescence of others in the industry that the patent is valid, and unexpected results. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18 (1966).

52. A party seeking to challenge the validity of a patent based on obviousness must also demonstrate by “clear and convincing evidence” that the invention described in the patent would have been obvious to a person of ordinary skill in the art at the time the invention was made.¹¹ *Pfizer, Inc. v. Apotex, Inc.*, 480 F.3d 1348, 1359-60 (Fed. Cir. 2007). However, in determining what would have been obvious to one of ordinary skill in the art at the time of invention, the use of hindsight is not permitted. *See KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. 398, 421, 127 S. Ct. 1727, 1742, 167 L. Ed. 2d 705, 724 (2007) (cautioning against “the distortion caused by *hindsight bias*” and “arguments reliant upon *ex post reasoning*” in determining obviousness) (emphasis added).

53. In *KSR*, the Supreme Court rejected a rigid application of the principle that there should be an explicit “teaching, suggestion, or motivation” in the prior art, the nature of the problem, or the knowledge of a person having ordinary skill in the art, in order to find obviousness. *See KSR Intern. Co. v. Teleflex Inc.*, 550 U.S. at 415. The *KSR* Court, however, acknowledged the importance of identifying “a reason that would have prompted a person of

¹¹ “Clear and convincing evidence is evidence that places in the fact finder ‘an abiding conviction that the truth of [the] factual contentions are ‘highly probable.’” *Alza Corp. v. Andrx Pharms., LLC*, 607 F. Supp. 2d 614, 631 (D. Del. 2009) (quoting *Colorado v. New Mexico*, 467 U.S. 310, 316 (1984)).

ordinary skill in the relevant field to combine the elements in the way the claimed new invention does' in an obviousness determination." *Takeda Chem. Indus. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. 2007) (quoting *KSR*, 550 U.S. at 418).

a. The Level of Ordinary Skill in the Art

54. A person of ordinary skill in the art with respect to the '834, '210, '337 and '873 patents is a person having a bachelor's or PharmD degree in pharmacy, pharmaceutical sciences, or related science disciplines; having three to five years of formulation experience; and being supervised by a Ph.D. or someone with substantially longer formulation experience. The person would likely be a member of a formulation development team that may include analytical chemists and related development scientists. One skilled in the art with respect to the '834, '210, '337 and '873 patents would know that it is important to develop a composition that will meet compendial and expected regulatory specifications for an ophthalmic solution.

55. A person of ordinary skill with respect to the '078 patent is a person having a bachelor's degree in chemistry, microbiology, or related science disciplines; having three to five years of antimicrobial chemistry experience; and being supervised by a Ph.D. or someone with substantially more experience in the field. The person of ordinary skill could work as part of a team to develop an antimicrobial formulation. One skilled in the art with respect to the '078 patent would know applicable regulatory guidelines for meeting preservation and disinfection requirements.

56. Applying these legal standards to the substantial evidence in the record, including the evidence presented at trial, and the prior art references cited in the parties' post-trial submissions, the court concludes that neither Apotex nor Exela has shown by clear and

convincing evidence that the asserted claims of the patents-in-suit are invalid as obvious over the prior art. *See PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342, 1360 (Fed. Cir. 2007) (explaining that when challenging the validity of a patent for obviousness based on a combination of prior art references, “the burden falls on the patent challenger to show by clear and convincing evidence that one of ordinary skill in the art would have had reason to attempt to make [the combination] . . . and would have had a reasonable expectation of success in doing so”).

b. The ‘834, ‘210, ‘337 and ‘873 Patents

57. The defendants have failed to prove by clear and convincing evidence that the ‘834, ‘210, ‘337 and ‘873 patents are obvious in light of the prior art. Apotex contends that the asserted claims of the ‘834, ‘210, ‘337 and ‘873 patents are invalid as obvious over the combination of Refresh Tears® and Alphagan P®. (D.I. 237 at 27.) In support of its obviousness contention, Apotex argues that one of ordinary skill in the art would have been motivated to combine Refresh Tears® with brimonidine for several reasons. First, Apotex argues that a person of ordinary skill in the art would have known that brimonidine was soluble within the claimed pH ranges. (D.I. 237 at 34.) Next, Apotex argues that a person of ordinary skill in the art would have expected CMC to increase the solubility of brimonidine in Refresh Tears®. (*Id.* at 35.) Apotex further argues that persons of skill in the art would have expected brimonidine to be compatible with the preservative Purite®. (*Id.* at 38.) Apotex also argues the relevant secondary considerations of non-obviousness are insufficient to overcome its claim of obviousness. (*Id.* at 40.) In addition, Exela argues the ‘834 patent is obvious over the combinations of several additional pieces of prior art not cited by Apotex. (D.I. 235 at 19-20.)

The court, however, is not persuaded by any of these arguments. Indeed, considering the scope and content of the prior art, there is substantial evidence in the record that supports the conclusion that one of ordinary skill in the art would not have been motivated to combine Refresh Tears® and Alphagan P®.

58. First, as Allergan correctly notes, at the time of these inventions, a person of ordinary skill in the art would have been aware of the limited solubility of brimonidine at the elevated pH of Refresh Tears®. Specifically, as Dr. Stella testified, because Refresh Tears® has a relatively high pH, ranging from 7.2 to 7.9, a person of ordinary skill in the art would not have expected effective concentrations of brimonidine to be soluble in that pH range. (D.I. 234 at 1636:19-1637:17.)

59. A person of ordinary skill in the art also would have known that it was desirable to formulate ophthalmic products at a pH close to that of the eye, *i.e.*, at or around 8.5; but that formulating at such a relatively high pH with brimonidine would be difficult due to issues relating to the limited solubility of brimonidine. Indeed, according to Apotex's own ophthalmology expert, Angelo P. Tanna, M.D. ("Dr. Tanna"), "there were many, many formulations that were unable to do that." (D.I. 229 at 492:7-18.) The court likewise finds, and the evidence supports, that at the time of invention there were "many, many" ophthalmic formulations that could not be formulated at the relatively high pH of the eye. (*Id.*)

60. Regarding the '834, '210, '337 and '873 patents, Dr. Olejnik testified that at the time he and Dr. Kerslake were developing the claimed formulation, they both had "concerns" and were surprised to discover that the brimonidine was not precipitating out at the high pH range of the claimed invention. (D.I. 227 at 145:7-148:3.) This testimony corroborates both the

testimony of Dr. Stella, and the other evidence adduced at trial concerning the limited solubility of brimonidine at high pHs. The court is, therefore, not convinced that a person of ordinary skill in the art would have known that brimonidine was soluble within the claimed pH ranges.

61. The court is also not convinced that the combination of prior art references upon which Exela relies supports its contention that the '834 patent is obvious. Specifically, the court is not persuaded that the combination of Alphagan P® and Refresh Tears® with the 1997 article by David Small (the "Small reference") addresses the known solubility issues with brimonidine at higher pH values. As Dr. Stella testified, the Small reference does not teach or suggest any of the claimed formulations. (D.I. 234 at 1654:13-19.) Indeed, nothing in the Small reference addresses the limited solubility of brimonidine at high pHs. (*Id.*) Moreover, contrary to Exela's assertion, the Small reference does not in any way suggest that it would have been possible to raise the pH of a brimonidine formulation above the 6.3 to 6.5 pH range at which brimonidine was known to be soluble in the claimed formulations. (*Id.*) The combination of Alphagan P® and Refresh Tears® with the Small reference would not have taught one of ordinary skill in the art anything to suggest that the claims of the '834 patent are obvious.

62. The court also is not persuaded that a person of ordinary skill in the art would have expected CMC to increase the solubility of brimonidine in Refresh Tears®. Apotex argues that, in view of the Loftsson prior art references, "a person of skill in the art would have been particularly motivated to utilize the solubilizing effect of CMC . . . to increase the solubility of topically applied ophthalmic active ingredients," including brimonidine. (D.I. 237 at 36.) The court disagrees. First, as Dr. Stella testified, the Loftsson references require the use of a heating method for solubility testing that is very different than that disclosed in the patents-in-suit. (D.I.

234 at 1617:12-1618:2, 1607:6-1608:3, 1736:8-1737:13.) Specifically, as described in the Loftsson references, and as admitted on cross-examination by Apotex's own expert, Gilbert S. Banker, Ph.D. ("Dr. Banker"), solubility testing is to be performed on samples "heated in an autoclave . . . in a sealed container to 120°C for 20 min." (D.I. 233 at 1411:13-22.)

63. In contrast, solubility testing, as disclosed in the patents-in-suit, is required to be performed at "room temperature (~21°C)." (D.I. 234 at 1618:3-1620:8.) The claims of the '834 patent also require the brimonidine in the formulation to be soluble at about 21°C. (*Id.*) Unlike the Loftsson references, the patents-in-suit do not require or involve in any way the use of an autoclave heating method for solubility testing.

64. Further, as Dr. Stella further points out, the Loftsson references do not disclose CMC as aiding the solubility of brimonidine. (D.I. 234 at 1615:23-1616:4, 1616:13-1617:11.) Indeed, none of the drugs discussed in the Loftsson references are even in the same drug class as brimonidine, *i.e.*, none are alpha-2-adrenergic agonists. Accordingly, the court is not persuaded by the Loftsson prior art references on the issue of whether a person of ordinary skill in the art would have expected CMC to increase the solubility of brimonidine in Refresh Tears®.

65. For similar reasons, the court also does not give much weight to any of the other prior art references Apotex cites in support of its position on this issue. Specifically, based on the scope and content of the prior art, the court is not convinced that the Higuchi reference would have taught a person skilled in the art anything about the use of CMC as a solubility enhancer with alpha-2-adrenergic agonists. (D.I. 234 at 1624:2-8.) The court is also not persuaded by either the Ajuha reference or the Burke '991 patent reference. As Dr. Banker conceded in his testimony, neither of these references address whether it would have been obvious to a person

skilled in the art to combine brimonidine with Refresh Tears® or use CMC as a solubility enhancer. (D.I. 233 at 1420:24-1421:3, 1414:25-1415:6.)

66. The court further concludes that a person of ordinary skill in the art would not have been motivated to combine Refresh Tears® and Alphagan P® due to concerns that the Purite® preservative in Refresh Tears® would oxidize the brimonidine in Alphagan P®. At trial, Allergan presented credible expert testimony on this very point. Specifically, Dr. Stella testified that at the time of these inventions, it was well-known in the art that: (1) the Purite® preservative was a “strong oxidant,” and that (2) the structural features of brimonidine made it particularly susceptible to oxidation. (D.I. 234 at 1636:25-1637:15.) Dr. Stella further explained that persons of skill in the art would not have used Purite® with brimonidine due to concerns that Purite® would very likely oxidize a brimonidine-based drug. (*Id.* at 1630:6-1632:1, 1633:24-1634:8.)

67. As corroborated by the testimony of Dr. Stella, these same concerns about brimonidine being oxidized by Purite® are documented in at least two reports prepared at the time of invention. (*See* JTX-044; JTX-035.) In addition, there is evidence in the record that, during the development of the claimed inventions, the inventors of the ‘210, ‘337, ‘834, and ‘873 patents also expressed concerns about using Purite® in a brimonidine formulation due to the potential for oxidation. In light of the substantial evidence in the record regarding known concerns that the Purite® preservative would oxidize brimonidine, the court is not persuaded that a person of skill in the art would have necessarily been motivated to combine Refresh Tears® and Alphagan P®.

68. The court is, likewise, not persuaded that the prior art references Apotex relies

upon support the conclusion that a person of skill would have expected brimonidine to be compatible with Purite®. For one thing, Apotex cites two of these references, U.S. Patent No. 5,725,887 (the “887 patent”) and U.S. Patent No. 6,358,935 (the “935 patent”), for the first time in its post-trial submissions. As Allergan correctly points out, Apotex offers no evidence to support its characterizations of these references or its conclusory assertions as to how these references supports its obviousness claims.

69. At trial, Apotex presented no expert testimony about either of these two references. Indeed, there is no expert testimony in the record that explains how these references would be viewed from the perspective of a person of ordinary skill in the art. The court is, therefore, left to rely solely on attorney argument to try to digest and discern any relevant teachings these references may or may not provide. *See Invitrogen Corp. v. Clontech Labs., Inc.*, 429 F.3d 1052, 1068 (Fed. Cir. 2005) (“Unsubstantiated attorney argument regarding the meaning of technical evidence is no substitute for competent, substantiated expert testimony.”) The court, likewise, finds the Thompson reference unpersuasive because, among other things, it teaches nothing about the oxidative stability of brimonidine in a Purite®-containing formulation that needs to be shelf-stable for two years. (D.I. 234 at 1630:6-1632:6.)

70. The court is equally unimpressed by the prior art references Exela cites concerning the combination of Purite® and brimonidine, *i.e.*, the Burke ‘991 patent or Alphagan P® in combination with the Frangione, Ripley, or Park patents. Particularly, given the testimony of Drs. Mitra and Stella regarding these prior art references, the court finds that none of these references, either alone or in combination, teach anything about whether one of ordinary skill in the art would have been motivated to combine Refresh Tears® and Alphagan P®. Both Apotex

and Exela have failed to present sufficient evidence to establish that a person of ordinary skill in the art would have expected brimonidine to be compatible with Purite®.

c. The '078 Patent

71. Apotex has also failed to prove by clear and convincing evidence that the '078 patent is obvious in light of the prior art. The field of invention claimed in the '078 patent is antimicrobial chemistry. The asserted claims of the '078 patent require: (1) the use of stabilized chlorine dioxide, (2) at a pH of about 6.8 to about 8.0, (3) as the sole preservative, and (4) for an ophthalmic formulation. (JTX-001 at 11:66-12:14.) Apotex argues that the '078 patent is obvious because it is nothing more than “a simple combination of Purite, a preservative known to be safe and effective in ophthalmic solutions, . . . [with] the FDA-mandated [Alphagan®] formulation and [and] industry-known template of preservative-buffer-tonicity component[s].” (D.I. 190, Tab 7.2 at 3.) The court disagrees. Given the field of invention and the asserted claims of the '078 patent, and considering the scope and content of the prior art, the court is not persuaded that the prior art references upon which Apotex relies establish by clear and convincing evidence that the '078 patent is obvious. These references do not disclose the use of stabilized chlorine dioxide at a pH of about 6.8 to about 8.0 as the sole preservative for an ophthalmic formulation, either alone or in combination.

72. The British Patent No. 1,275,885 (the “GB '885 patent”) also does not disclose the use of stabilized chlorine dioxide as a preservative, as claimed in the '078 patent. (D.I. 233 at 1490:4-1491:16.) In contrast to the '078 patent, the GB '885 patent is directed to a liquid antacid composition generated by chlorine dioxide in solution; that uses chlorine dioxide (not stabilized chlorine dioxide) as a preservative. (DTX-277 at 1.) The GB '885 patent also does not disclose

the pH limitations claimed in the '078 patent. (D.I. 190, Tab 7.1 at 41.) Moreover, the pH levels that are discussed in the GB '885 patent are incapable of reducing or converting chlorine dioxide to stabilized chlorine dioxide. (*Id.*) In addition, the GB'885 patent does not disclose the ophthalmic formulation limitation because, among other things, it does not teach or suggest any compositions that can be safely applied to the eye. (*Id.*) As such, the court is not convinced that this reference renders the claims of the '078 patent obvious.

73. The other prior art references cited by Apotex also do not teach the inventions claimed in the '078 patent. Admittedly, U.S. Patent No. 4,689,215 (the "Ratcliff '215 patent") discloses stabilized chlorine dioxide as a starting material, and the use of chlorine dioxide as the active antimicrobial species for ophthalmic applications. (DTX-118 at Examples I-VIII.) Unlike the '078 patent, however, it does not teach the use of chlorite or unactivated stabilized chlorine dioxide as an antimicrobial agent. (D.I. 234 at 1524:19-22.) The Ratcliff prior art reference also does not address either the claimed pH range or the osmolality limitations disclosed in the asserted claims of the '078 patent. (D.I. 190, Tab 7.1 at 37.)

74. For similar reasons, U.S. Patent No. 4,499,077 (the "Stockel '077 patent") also does not teach any of the claimed inventions disclosed in the '078 patent. Specifically, the Stockel '077 patent describes an antimicrobial composition for disinfecting contact lenses that requires both "an oxyhalogen compound and a polymeric germicide." (DTX-252 at Abstract; D.I. 234 at 1597:15-25.) The Stockel reference, however, does not attribute antimicrobial activity to unactivated stabilized chlorine dioxide. (D.I. 234 at 1590:25-1591:2; D.I. 230 711:5-16.) Thus, in essence, it actually teaches away from the from the stabilized chlorine dioxide "as the sole preservative" limitation in the claimed invention.

75. The court further concludes that neither the FDA Notice of Proposed Rulemaking (the “FDA Notice”) nor the 1983 Bio-Cide letter make the asserted claims of the ‘078 patent obvious. (D.I. 234 at 1525:25-1526:15; DTX-216.) For one, the FDA Notice provides no information on how to select a preservative. (D.I. 234 at 1525:25-1526:15.) It also does not address the use of chlorine dioxide or stabilized chlorine dioxide in an eyewash. (*Id.*) Similarly, the 1983 Bio-Cide letter provides no information that would have given a person of ordinary skill in the art reason to make or attempt to make the patented invention. In addition, the court’s view is not altered by Apotex’s citation to U.S. Patent Nos. 2,271,242 and U.S. 2,546,179, or the Anthium Dioxocide label prior art references.¹²

76. Indeed, none of the foregoing prior art references, either alone or in combination, show by clear and convincing evidence that the ‘078 patent is obvious in light of the prior art. The court, therefore, rejects Apotex’s obviousness claims in this regard.

d. Secondary Considerations of Non-Obviousness

77. There is substantial evidence in the record of several relevant secondary considerations that further support a finding of non-obviousness. *See Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1538 (Fed. Cir. 1983) (noting that “evidence of secondary considerations may often be the most probative and cogent evidence in the record”). Specifically, Allergan presented both expert testimony and documentary evidence chronicling: (1) the failures of others in the market to successfully design around the patent-in-suit; (2) others’ efforts to reformulate and copy the claimed formulations; (3) the long-felt need in the market at the time for a product,

¹² The court notes that Apotex’s presented no direct expert testimony concerning the ‘179 prior art reference at trial. Instead, the ‘179 patent was raised by Apotex only during the cross-examination of Allergan’s expert, Dr. Gordon.

such as the claimed formulation, to address the high rate of allergic reaction in certain patients; (4) the unexpected results produced by the claimed inventions and the skepticism by those in the scientific and medical communities at the time of invention; (5) the commercial success of the claimed formulations; and (6) the nexus between the commercial success and the claimed invention. (Trial Tr. at 529-54, 1658-67.)

78. For example, on the issue of commercial success, it is undisputed that in 2008 the Alphagan P® products covered by the patents-in-suit had sales of approximately \$240 million. (*Id.* at 534.) It is also undisputed that since generic brimonidine 0.2% products came on the market in June 2003, the Alphagan P® products have maintained 85-90% of the market share for brimonidine products. (*Id.* at 551-52.) Accordingly, the court, finds that all of the relevant secondary considerations support the conclusion that the patents-in-suit are not invalid as obvious over the prior art.

79. In sum, the court is not persuaded that the defendants have established by clear and convincing evidence that the patents-in-suit are obvious in light of the prior art. The court finds that there are significant differences between the prior art and the claimed inventions, such that a person of ordinary skill in the art would not have been motivated to combine Refresh Tears® and Alphagan P®. In addition, there exist a number of secondary considerations that severely undermine the defendants' claims of obviousness. Accordingly, the court concludes that the patents-in-suit are not invalid as obvious under 35 U.S.C. § 103.

ii. Non-Enablement

80. Section 112 requires that a patent specification contain "exact terms as to enable" a person of ordinary skill in the relevant art to make and use the claimed invention. 35 U.S.C. §

112, ¶ 1. Moreover, “the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation.” *In re Wright*, 999 F.2d 1557, 1561 (Fed. Cir. 1993) (internal quotations omitted).

81. In determining whether “undue” experimentation is required to make and use a claimed invention, courts may consider the following factors:

(1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

In re Wands, 858 F.2d 731, 737 (Fed. Cir. 1988). Although the question of undue experimentation entails many factual considerations, enablement remains a question of law. *Id.* at 735.

82. Here, Apotex argues that the asserted claims of the ‘210, ‘834, ‘337, and ‘873 patents are invalid for failing to satisfy the enablement requirements of 35 U.S.C. § 112. (D.I. 190, Tab 7.2 at 75.) In addition, Exela argues that the ‘834 patent is invalid because, among other things, “[e]nabling the full scope of the ‘834 patent claims would require undue experimentation.” (D.I. 235 at 15-16.) In support of its argument, Exela relies largely on the testimony of its expert, Dr. Mitra. (D.I. 233 at 1442:11-1443:9.) Specifically, Dr. Mitra testified that the ‘834 patent claims were not sufficiently enabled because one of skill in the art would not understand either: (1) the lower limit of “up to about 0.15%” brimonidine concentration or (2) the upper limit of “a pH of about 7.0 and greater.” (D.I. 231 at 1020:11-21, 1026:16-1027:19.) The court disagrees.

83. Indeed, there is substantial evidence in the record that undermines the non-enablement opinion offered by Dr. Mitra. First, as Dr. Stella noted in his testimony, with respect to the brimonidine concentration, one of skill in the art would have been fully aware of the Alphagan® product that was on the market at the time, as well as the brimonidine concentration and efficacy of that product. (D.I. 244 at 1644:21-1647:21.) In contradicting Dr. Mitra's testimony on the issue of enablement, Dr. Stella testified that a person of ordinary skill would have been able to compare a proposed formulation with Alphagan® to determine whether a selected drug concentration was therapeutically effective, as disclosed in the '834 patent. (*Id.*)

84. Second, as to whether one of skill in the art would understand the "a pH of about 7.0 and greater" limitation, Dr. Stella explained that, because the acceptable physiological pH of the eye is up to about 8.5, one of skill in the art would know that a formulation with a pH of greater than about 7.0 could go up as high as 8.5. (D.I. 234 at 1644:21-1647:21.) As such, the court is not convinced that undue experimentation is required to make and use any of the claimed inventions covered in the patents-in-suit.

85. Based on the substantial evidence in the record on this issue, including the testimony of both Drs. Mitra and Stella, as well as the evidence cited in the parties' post-trial submissions, the court finds that the defendants have not demonstrated by clear and convincing evidence that the patents-in-suit are invalid for lack of enablement under 35 U.S.C § 112.

iii. Written Description

86. The court also finds that the defendants have failed to prove by clear and convincing evidence that any of the patents-in-suit are invalid for failing to meet the written description requirement under 35 U.S.C. § 112.

87. Section 112 requires a “written description of the invention” which is separate and distinct from the enablement requirement. *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563 (Fed. Cir. 1991) (quoting 35 U.S.C. § 112, ¶ 1). The purpose of the written description requirement is broader than to merely explain how to make and use the claimed invention. *Id.* at 1563-64. The applicant must also convey with reasonable clarity to those skilled in the art that, as of the filing date of the patent, he or she was in possession of the claimed invention. *Id.*

88. Here, both defendants argue that certain of the patents-in-suit are invalid for failure to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1. In particular, Apotex argues that the ‘210, ‘834, ‘337, and ‘873 patents fail to meet this § 112 requirement. (D.I. 190, Tab 7.2 at 75.) Exela argues that the ‘834 patent fails to meet the written description requirement because the specification does not have written descriptive support for “the later claimed sub-genera of therapeutically effective brimonidine tartrate compositions not requiring a solubility enhancing component . . . and defined by the concentration ranges inclusive of 0.15%, and pH ranges inclusive of 7.0.” (D.I. 235 at 12.)

89. The court disagrees. As Allergan correctly notes, Exela presented no expert testimony to support this argument at trial.¹³ On the other hand, two of Allergan’s witnesses provided testimony that undercuts Exela’s position. Specifically, both Drs. Olejnik and Stella testified that in their view as persons skilled in the art: (1) the claimed invention is fully disclosed in the original specification and claims of the ‘834 patent, and (2) as of the filing date of the patent, the inventors of the ‘834 patent were, indeed, in possession of the claimed invention.

¹³ Note that the testimony of Exela’s written description witness, Dr. Delamere, was stricken from the record at trial because, as Dr. Delamere admitted, he is not “one of ordinary skill in the art.” (D.I. 231 at 960:15-962:8.)

(D.I. 228 at 275:3-276:2; D.I. 234 at 1641:17-1643:25.)

90. The court, therefore, concludes that neither Apotex nor Exela has established by clear and convincing evidence that the patents-in-suit are invalid for failure to comply with the written description requirement of 35 U.S.C. § 112, ¶ 1.

iv. Best Mode

91. A patent is invalid if the specification does not describe the “best mode contemplated by the inventor of carrying out his invention.” *See* 35 U.S.C. § 112, P 1. The “purpose of this . . . requirement is to restrain inventors from applying for patents while at the same time concealing from the public preferred embodiments of their inventions which they have in fact conceived.” *See In re Gay*, 50 C.C.P.A. 725, 309 F.2d 769, 772 (1962). Because the record does not support a best mode violation by Allergan, the court will decline to invalidate the patents-in-suit on this basis.

92. Determining whether a patent satisfies the best mode requirement involves a two-part factual analysis. *See Eli Lilly and Co. v. Barr Lab.*, 251 F.3d 955, 963 (Fed. Cir. 2001) (citing cases). First, the court, as the factfinder, must determine whether, at the time the patent application was filed, the inventor had a best mode of practicing the claimed invention. *Id.* (citing cases). This inquiry is wholly subjective and focuses on the inventor’s state of mind at the time of filing to determine whether he or she must disclose any facts in addition to those sufficient for enablement. *Id.*

93. Second, if the inventor had a best mode of practicing the claimed invention, the court, again as the factfinder, must then determine if the specification adequately disclosed what the inventor contemplated as the best mode so that those having ordinary skill in the art could

practice it. *See Eli Lilly*, 251 F.3d at 963. This inquiry is an objective one that depends upon the scope of the claimed invention and the level of skill in the art. *Id.* Because patents are presumed valid, *see* 35 U.S.C. § 282, the defendants must establish a best mode violation by clear and convincing evidence. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1064 (Fed. Cir. 1998).

94. Here, both defendants allege that the patents-in-suit are invalid for failure to disclose the best mode. Specifically, Apotex contends that the '210, '834, '337 and '873 patents are invalid because "Allergan failed to disclose the best mode of carrying out the inventions." (D.I. 190, Tab 7.2 at 56.) In support of this contention, Apotex argues that, despite finalizing the claimed Alphagan P® 0.15% formulation prior to filing the patents-in-suit, and marketing it to the ophthalmology community as an "optimized" formulation over Alphagan®, Allergan never included this formulation in the specification for any of these patents. (*Id.* at 56.)

95. Exela contends that the '834 patent is invalid because the "patentees had a best mode for practicing their invention, but they did not adequately disclose the best mode in the patent specification." (D.I. 235 at 9-10.) Relying on the testimony of its expert, Dr. Mitra, Exela argues that Alphagan P® 0.15% was the inventors' best mode for the claimed invention at the time the patent applications were filed, but that Allergan did not disclose this formulation in the '834 patent. (*Id.* at 10-11.)

96. After having considered the substantial evidence in the record, the parties contentions, and the applicable legal standard, the court concludes that the defendants have failed to show by clear and convincing evidence that any of the asserted claims of the patents-in-suit are invalid for failure to disclose a best mode under 35 U.S.C. § 112. First, the court is not

persuaded that, at the time the patent applications were filed, that any of the inventors actually had a best mode of practicing the claimed inventions in mind. Neither of the inventors on the patents-in-suit testified as to having had a best mode in mind when they filed the application for the '834 patent.

97. In addition, and contrary to the defendants' arguments, the court finds that the record lacks sufficient factual support to conclude that the best mode for the claimed inventions was, in fact, a formulation containing 0.15% brimonidine. As Allergan correctly notes, this argument is undermined by the fact that Allergan continued to develop its invention, and ultimately developed a 0.1% formulation. Moreover, both Drs. Stella and Olejnik testified that, at the time the patents-in-suit were filed, a person of ordinary skill in the art would have considered the 0.15% brimonidine formulation fully disclosed. (D.I. 234 at 1640:21-1643:25; D.I. 228 at 225:3-276:2.) Indeed, it is noteworthy that these men of skill in the art both found the 0.15% brimonidine formulation in the specification.

98. The court concludes then that the defendants have failed to show by clear and convincing evidence that the '210, '834, '337 and '873 patents are invalid for failure to disclose the best mode.

v. **Indefiniteness**

99. Section 112 of the patent statute requires that patent claims "particularly point[] out and distinctly claim[] the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2. In determining whether a claim is sufficiently definite, courts analyze whether one skilled in the art would understand the bounds of the claim when read in light of the specification. *See Allen Eng'g Corp. v. Bartell Indus.*, 299 F.3d 1336, 1348 (Fed. Cir. 2002)

(quotations omitted).

100. The defendants have not shown by clear and convincing evidence that any of the asserted claims of the patents-in-suit are invalid for indefiniteness under 35 U.S.C. § 112. Neither Apotex nor Exela has presented competent expert testimony to support any such finding. Indeed, Apotex offered no expert testimony on this issue at trial, and the testimony offered by Exela's witness was stricken by the court because, among other things, the witness was admittedly not one of ordinary skill in the art. (*See* ¶ 89 above.) Thus, there is insufficient evidence in the record to invalidate any of the patents-in-suit for indefiniteness. The court must, therefore, reject the defendants' arguments in this regard.

vi. Utility and Operability

101. Section 101 of the patent statute requires that a patent be "useful." *See* 35 U.S.C. § 101 ("Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.").

102. In order for an invention to be considered "useful," the invention must have both "substantial" and "specific" utility. *See In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005). In order "to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public." *Id.* at 1371. To satisfy the "specific" utility requirement, "an asserted use must [] show that the claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.* at 1371.

103. The utility requirement means that a patentable invention must be operable to achieve useful results. *See Brooktree Corp. v. Advanced Micro Devices, Inc.*, 977 F.2d 1555,

1571 (Fed. Cir. 1992). Where the number of inoperative claimed combinations becomes significant, one of ordinary skill in the art is forced to unduly experiment in order to practice the claimed invention, and hence the claims may be invalid. *See Atlas Powder Co. v. E.I. du Pont de Nemours & Co.*, 750 F.2d 1569, 1576-77 (Fed. Cir. 1984).

104. Here, Apotex argues that the ‘210, ‘834, ‘337, and ‘873 patents are invalid, and Exela argues that the ‘834 patent is invalid, for failing to meet the utility and operability requirements of 35 U.S.C. § 101. (D.I. 190, Tab 7.2 at 77; D.I. 190, Tab 7.3 at ¶ 362.)

105. More specifically, Exela argues that the majority of the embodiments of claims 1-4, 6, 8-13 and 17-21 of the ‘834 patent are inoperable under 35 U.S.C. § 101. (D.I. 190, Tab 7.3 at ¶ 362.) The court disagrees. There is insufficient evidence in the record to support this finding. In its submissions to the court, Exela cites no expert testimony in the record that supports this contention. Indeed, as far as the court can tell, Exela’s arguments for lack of utility and inoperability rest solely on attorney argument. This is simply not enough to invalidate any of the patents-in-suit.

106. The court therefore concludes that the defendants have failed to meet their burden of proving by clear and convincing evidence that any of the asserted claims of the patents-in-suit are invalid for failing to meet the utility and operability requirements of 35 U.S.C. § 101.

vii. Inventorship

107. Under § 102 of the patent statute, a patent is invalid if it fails to properly identify the correct inventor of the claimed invention. *See* 35 U.S.C. § 102(f) (noting that a person may receive a patent unless, among other things, “he [or she] did not invent the subject matter sought to be patented.”). *See also Pannu v. Iolab Corp.*, 155 F.3d 1344, 1351 (Fed. Cir. 1998)

("[S]ection 102 still makes the naming of the correct inventor or inventors a condition of patentability; failure to name them renders a patent invalid."). Moreover, to be an inventor, a person must contribute to the conception of the claimed invention. See *Burroughs Wellcome Co. v. Barr Labs., Inc.*, 40 F.3d 1223, 1227-28 (Fed. Cir. 1994).

108. Here, Apotex contends that it has shown by clear and convincing evidence that: (1) "Anthony J. Dziabo and Paul S. Ripley are not the inventors of the subject matter claimed in the '078 patent" and that (2) "the '078 patent is invalid for failing to name the proper inventors pursuant to 35 U.S.C. § 102(f)." (D.I. 190, Tab 7.2 at 78.) The court disagrees. Based on substantial evidence in the record, the court finds that both Dziabo and Ripley are properly identified as the correct inventors of the subject matter claimed in the '078 patent.

109. The record reflects that, in developing the claimed invention, both Dziabo and Ripley conducted extensive experiments with Purogene® for ophthalmic disinfectant applications, and that the results from those experiments showed that Purogene® failed as a disinfectant. (D.I. 229 at 615:9-616:12, 619:20-620:20.) The record further reflects that Dziabo and Ripley analyzed the chemical properties of Purogene®, and independently determined that it was a solution of very pure chlorite ion. (*Id.*)

110. In addition, there is substantial evidence in the record indicating that, after studying and working with Purogene®, Dziabo and Ripley conceived of using diluted, unactivated Purogene®, *i.e.*, chlorite as a preservative. The court can find no record evidence that contradicts the conclusion that the idea was Dziabo's and Ripley's alone. (D.I. 229 at 634:5-21, 650:19-651:3.) Thus, the court is persuaded that the invention claimed in the '078 patent is, indeed, the result of Dziabo's and Ripley's extensive study of the chemical properties of

Purogene®, including its toxicity, antimicrobial effects, pH-dependency, and osmolality, as well as their understanding of its behavior. (*Id.* at 634:5-21.)

111. The court, however, is not persuaded that Bio-Cide personnel are the correct inventors as Apotex asserts, or that Bio-Cide contributed in any way to the conception of the invention claimed in the '078 patent. There simply is no definitive evidence in the record to support such a finding. As Allergan notes, the record suggests that the views, if any, that Bio-Cide held concerning Purogene® at the time, teach away from the invention conceived by Dziabo and Ripley. For example, in contrast to the claimed invention, the record reflects that Bio-Cide incorrectly attributed the killing power of Purogene® to the production of chlorine dioxide, known to be an unsuitable preservative, resulting from the Purogene's® activation. (D.I. 234 at 1525:16-20.) Regarding the significance of the 1983 Bio-Cide letter to this inquiry, the court credits the testimony of Dziabo, who explained that: (1) he saw the letter for the first time at his deposition in this case and (2) he understood the letter as referring to an Allergan contact lens disinfectant product containing both thimerisol and quaternium as antimicrobial agents. (D.I. 230 at 713:24-714:18.)

112. Given this record, the court can not find that Apotex has proven by clear and convincing evidence that any of the asserted claims of the '078 patent run afoul of the requirements of 35 U.S.C. § 102(f).

C. Unenforceability

113. The court is, likewise, not convinced that Apotex has proven by clear and convincing evidence that the asserted claims of the '078 patent are unenforceable due to inequitable conduct.

114. “Inequitable conduct includes affirmative misrepresentation of a material fact, failure to disclose material information, or submission of false material information, coupled with an intent to deceive.” *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1178 (Fed. Cir. 1995). To successfully prove inequitable conduct, the accused infringer must prove by clear and convincing evidence at least a threshold level of both materiality and intent to deceive. *Larson Mfg. Co. of South Dakota, Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1326 (Fed. Cir. 2009).

115. Here, Apotex argues that Allergan committed inequitable conduct during the prosecution of the patent applications resulting in the issuance of the ‘078 patent. (D.I. 190, Tab 7.2 at 80.) Specifically, Apotex argues that during the prosecution of the ‘078 patent Allergan: (1) misrepresented both the Stockel ‘208 patent¹⁴ and the Ratcliff ‘215 patent prior art references to the PTO, and (2) withheld information material to the patentability of the ‘078 patent from the PTO with an intent to deceive the PTO. (*Id.* at 17, 19.) The court disagrees.

116. There is insufficient evidence in the record to support a finding that Allergan misrepresented any prior art references to the PTO at any time during the prosecution of the ‘078 patent. Absent more, the testimony of Apotex’s expert, Dr. Banker is simply not enough to support such a finding.

117. The court is also not persuaded that Allergan withheld any information material to the patentability of the ‘078 patent from the PTO with an intent to deceive the PTO. For example, contrary to Apotex’s allegation that Allergan withheld information from the PTO about a patent application filed by Bio-Cide (the “Bio-Cide Danner application”), the prosecution history of the ‘078 patent reflects that the patent examiner was, indeed, fully aware of the Bio-

¹⁴ *I.e.*, U.S. Patent No. 4, 654,208 (the “Stockel ‘208 patent”)

Cide Danner patent application. (D.I. 233 at 1444:20-1445:10; JTX-075 at AI0017352-54.) Indeed, the record reflects that the Bio-Cide Danner application was before the same examiner, on the same day, facing the same patentability rejection, as the application for the '078 patent. (*Id.* at 33.) There is also no evidence in the record demonstrating, or that even suggests, any intent to deceive the examiner on the part of Allergan.

119. Based on the substantial evidence in the record, the court finds that Apotex has failed to prove by clear and convincing evidence that the '078 patent is unenforceable due to inequitable conduct.

D. Attorneys' Fees and Costs

120. Because the court does not find this case to be exceptional by clear and convincing evidence as required by 35 U.S.C. § 285, the court will not award attorneys' fees and costs.

121. In deciding whether to award attorney's fees, the court must undertake a two-step inquiry. *Interspiro USA, Inc. v. Figgie Intern. Inc.*, 18 F.3d 927, 933 (Fed. Cir. 1994). First, the court "must determine whether there is clear and convincing evidence that the case is 'exceptional.'" *Id.* (quotation omitted). Second, the court must determine whether "an award of attorney fees to the prevailing party is warranted." *Id.* Exceptional cases include: "inequitable conduct before the PTO; litigation misconduct; vexatious, unjustified, and otherwise bad faith litigation; a frivolous suit or willful infringement." *Epcon Gas Sys., Inc. v. Bauer Compressors, Inc.*, 279 F.3d 1022, 1034 (Fed. Cir. 2002) (citation omitted).

122. An award of attorney fees under § 285 is not intended to be an "ordinary thing in patent cases," and should be limited to circumstances in which it is necessary to prevent "a gross

injustice” or bad faith litigation. *Forest Labs., Inc. v. Abbott Labs.*, 339 F.3d 1324, 1329 (Fed. Cir. 2003); *see also Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) (affirming an award of attorney fees under § 285 for the “extreme litigation misconduct” of falsifying evidence); *Beckman Instruments, Inc. v. LKB Produkter AB*, 892 F.2d 1547 (Fed. Cir. 1989) (affirming an award under § 285 following repeated violations of a permanent injunction and a district court finding of a “strategy of vexatious activity”).

123. The defendants’ conduct in this case does not rise to a level of bad faith or vexatious litigation that warrants an award of attorneys’ fees and costs. Indeed, the record demonstrates that throughout this litigation, both sides vigorously, and in apparent good faith, defended their respective positions. *See Forest Labs., Inc. v. Ivax Pharms., Inc.*, No. 03-891-JJF, 2008 U.S. Dist. LEXIS 14623, at *6-7 (D. Del. Feb. 26, 2008) (noting that “hard-fought” litigation does not necessarily constitute “vexatious or bad faith litigation” for purposes of awarding attorney fees under § 285). The court therefore finds that none of the parties are entitled to an award for attorneys’ fees and costs in this case.

E. The Rule 52(c) Motions

124. Under Fed. R. Civ. P. 52(c), the court has discretion to enter judgment on any issue after hearing the evidence. *United Techs. Corp. v. Chromalloy Gas Turbine Corp.*, 105 F. Supp. 2d 346, 355 (D. Del. 2000). The rule provides that “[i]f a party has been fully heard on an issue during a nonjury trial and the court finds against the party on that issue, the court may enter judgment against the party on a claim or defense that, under the controlling law, can be maintained or defeated only with a favorable finding on that issue.” Fed. R. Civ. P. 52(c). The rule does not require the court to consider the evidence in the light most favorable to the

nonmoving party. *United Techs.*, 105 F. Supp. 2d 346 at 355-56 (citations omitted). Rather, the court weighs the evidence and assesses the credibility of witnesses to determine whether or not the plaintiff has demonstrated a factual and legal right to relief by a preponderance of the evidence. *Id.* at 356 (citing *Rego v. ARC Water Treatment Co. of PA*, 181 F.3d 396, 399 (3d Cir. 1998)).

i. Allergan's Rule 52(c) Motion

125. In its Rule 52(c) motion, Allergan moves for judgment as a matter of law regarding prior art references or combinations of references not raised at trial. (D.I. 244 at 1.) Specifically, Allergan argues that Apotex raises obviousness arguments in its post-trial submissions based on numerous prior art references and combinations of references that were not discussed or referred to by any witness at trial. (*Id.*) Allergan contends that, because these references are not supported by any expert testimony, Allergan is entitled to judgment as a matter of law as to Apotex's obviousness arguments that involve these new exhibits. (*Id.*) *See Koito Mfg. Co., Ltd. V. Turn-Key-Tech, LLC*, 381 F.3d 1142, 1151-52 (Fed. Cir. 2004) ("Koito entered the JP '082 reference into evidence, but otherwise failed to provide any testimony or other evidence that would demonstrate to the jury how that reference met the limitations of the claims in the '268 patent"); *see also Schumer v. Laboratory Computer Systems, Inc.*, 308 F.3d 1304, 1315-16 (Fed. Cir. 2002) ("Typically, testimony concerning anticipation must be testimony from one skilled in the art [.]").

126. The court is persuaded by Allergan on this point. The court will therefore grant Allergan's motion.

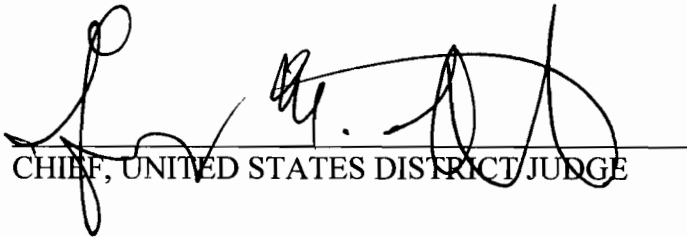
ii. Exela's Rule 52(c) Motion

127. In its Rule 52(c) motion, Exela requests a ruling that it does not infringe the '834 patent. (D.I. 223 at 1.) As explained in detail above, the court concludes that Exela's accused product literally infringes all of the asserted claims of the '834 patent. The court therefore denies Exela's motion.

IV. CONCLUSION

For the reasons stated above, the court concludes that: (A) the defendants' proposed generic products literally infringe the asserted claims of the patents-in-suit; (B) the patents-in-suit are not invalid; (C) the patents-in-suit are not unenforceable; (D) an award for attorneys' fees and costs is not warranted in this case; (E) Allergan's Rule 52(c) motion is granted, and Exela's Rule 52(c) motion is denied. An appropriate order will follow.

Dated: October 23, 2009



CHIEF, UNITED STATES DISTRICT JUDGE

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

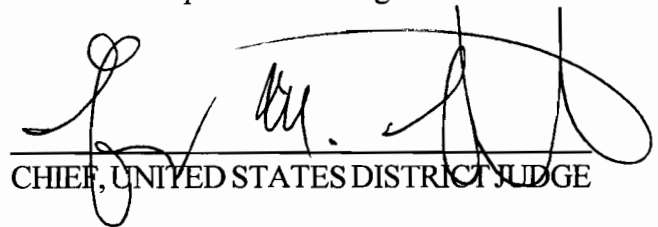
IN RE: BRIMONIDINE PATENT
LITIGATION

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) MDL Docket No. 07-md-1866 GMS
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ORDER

At Wilmington, this 23rd day of October, 2009, consistent with the memorandum opinion issued this same date, IT IS HEREBY ORDERED THAT:

1. The defendants' ANDA products infringe the asserted claims of the patents-in-suit.
2. The defendants have failed to prove the invalidity of the patents-in-suit by clear and convincing evidence.
3. Exela's Rule 52(c) motion (D.I. 223) motion is DENIED.
4. Allergan's Rule 52(c) motion (D.I. 244) is GRANTED.
5. An award for attorneys' fees and costs is not warranted in this case.
6. The Clerk of Court is directed to enter judgment in favor of plaintiffs and against defendant.



CHIEF, UNITED STATES DISTRICT JUDGE